K033487

DEC 2 4 2003

Summary of Safety and Effectiveness Information

This safety and effectiveness summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: George M. Plummer
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: October 31, 2003

Name of Product: Stratus® CS ™ Troponin I TestPak

FDA Classification Name: Immunoassay Method, Troponin Subunit

Predicate Device: Dade Behring Stratus® CS cTnI TestPak(K984093/K981098).

Intended Use:

The Stratus® CS Acute Care™ Troponin I method is an *in vitro* diagnostic test for the measurement of cardiac troponin I in heparinized plasma. Cardiac troponin I measurements can be used as an aid in the diagnosis of myocardial infarction. Cardiac troponin I can also be used as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Comparison to Predicate Device:

The Stratus® CS Acute Care™ Troponin I TestPak is substantially equivalent in intended use, principle and performance to the current Dade Behring Stratus® CS cTnI TestPak. Both assays are *in vitro* immunoassays with an intended use as an aid in the diagnosis of acute myocardial infarction and risk stratification of patients with acute coronary syndrome.

There are no formulation or design changes associated with the Stratus® CS cTnI TestPak labeling change. The two products are identical and use the same manufacturing processes. Only the insert sheets contain different information. The table on the next page summarizes the changes in the revised product insert sheet.

Item	Revised Insert Sheet Change
Method Name (throughout insert sheet)	Stratus® CS Acute Care™ Troponin I
Test Steps	Clarification of steps performed automatically allowed removal of Results section
Interpretation of Results	1. Added National Academy of Clinical Biochemistry statement 2. Added statement on results interpretation in conjunction with medical history 3. Moved some statements from the Diagnosis of AMI section 4. Added statements on institutions establishing own reference interval and other conditions which can led to myocardial injury
Reference Interval	Presentation of 97.5th and 99th percentile results instead of the 95th percentile
Risk Stratification	Added American College of Cardiology (ACC)/AHA definition for short term risk of death/non-fatal MI
Diagnosis of AMI	1. Added sensitivity/specificity graph 2. Added EU Society of Cardiology/ACC statement on MI definition 3. Added functional sensitivity information at 99th percentile
Performance Characteristics	Added plasma pool reproducibility data
Correlation Data	Added performance comparison versus Dade Behring Dimension® clinical chemistry system
Recovery	Clarified titles in chart
Bibliography	Added references

The source data used to support the insert sheet changes is listed below:

1. The lower risk stratification concentration for 0.1ng/mL is based on recommendations from the American College of Cardiology (ACC), American Heart Association and multiple hospital clinical studies.
2. Internal and external reference interval studies provided the stated 97.5th and 99th percentiles
3. Low-end, functional sensitivity precision studies indicate a high sensitivity method

Conclusion:

The Stratus® CS Acute Care™ Troponin I TestPak is substantially equivalent in principle and performance to the current Dade Behring Stratus® CS cTnI TestPak

George M. Plummer
Regulatory Affairs and Compliance Manager
October 31, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 4 2003

Mr. George M. Plummer
Affairs & Compliance Manager
Dade Behring, Inc.
Chemistry/Immunochemistry
Glasgow Business Community
P.O. Box 6101 – Bldg. 500
Newark, DE 19714

Re: k033487
Trade/Device Name: Stratus® CS Acute Care™ Troponin I TestPak
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: October 31, 2003
Received: November 21, 2003

Dear Mr. Plummer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K 033487

Device Name:

Stratus® CS Acute Care™ Troponin I TestPak

Indications for Use:

The Stratus® CS Acute Care™ Troponin I method is an *in vitro* diagnostic test for the measurement of cardiac troponin I in heparinized plasma. Cardiac troponin I measurements can be used as an aid in the diagnosis of myocardial infarction. Cardiac troponin I can also be used as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CRF 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033487